Author(s): AT/RPR/VS
Date: 2015-03-30
Question: Should manual tactile stimulation vs no treatment be used for reducing vaccine injection pain in people of all ages?
Settings: hospital, school, clinic
Bibliography: Chung 2002, Hogan 2014 (2011 thesis), Jose 2012, Nakashima 2013, Sparks 2001 (1) (1998 thesis), Taddio 2014 a

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Manual tactile stimulation	No treatment	Relative (95% CI)	Absolute		
Pain (measured with: validated tools (Oucher Pain Scale 0-5, Visual Analog Scale 0-10, Faces Pain Scale 0-10, Pain Intensity Verbal Rating Scale 0-10); Better indicated by lower values)												
3	randomised trials[1]	very serious[2,3]	serious[4]	no serious indirectness	serious[5]	none	441	452	-	SMD 0.38 lower (0.96 lower to 0.21 higher)	⊕OOO VERY LOW	CRITICAL
Distress Acute[6,7] (measured with: validated tools (Modified Behavioural Pain Scale 0-10, Visual Analog Scale 0-10, cry duration, Behavioural Pain Score 0-20) by parents/researchers; Better indicated by lower values)												
3	randomised trials	very serious[6,8]	serious[9]	no serious indirectness	serious[10]	none	152	149	-	SMD 0.69 lower (1.77 lower to 0.39 higher)[6,7]	⊕OOO VERY LOW	CRITICAL
Distress Acute (yes/no) (assessed with: validated tool (Modified Behavioural Pain Scale dichotomized, yes/no) by researcher)												
1	randomised trials	serious[11]	no serious inconsistency	no serious indirectness	serious[10]	none	56/62 (90.3%)	57/59 (96.6%)	RR 0.93 (0.85 to 1.03)	68 fewer per 1000 (from 145 fewer to 29 more)	⊕⊕OO LOW	CRITICAL
Distress Acute + Recovery (measured with: validated tools (Cry duration) by researcher; Better indicated by lower values)												
1	randomised trials	no serious risk of bias[11]	no serious inconsistency	no serious indirectness	serious[10]	none	62	59	-	SMD 0.15 lower (0.51 lower to 0.2 higher)	⊕⊕⊕O MODERATE	CRITICAL
Distress Pre-procedure (post-intervention) (measured with: validated tools (Modified Behavioural Pain Scale 0-10, Visual Analog Scale 0-10, Cry duration) by												

parents/researchers; Better indicated by lower values)												
2	randomised trials	serious[6,11]	no serious inconsistency	no serious indirectness	serious[10]	none	122	119	-	SMD 0.25 higher (0.08 lower to 0.59 higher)	⊕⊕OO LOW	CRITICAL
Parent Use of Intervention (assessed with: observation on the use of tactile stimulation by researcher)												
1	randomised trials	serious[6,11]	no serious inconsistency	no serious indirectness	serious[10]	none	59/60 (98.3%)	2/60 (3.3%)	RR 29.5 (7.55 to 115.28)	950 more per 1000 (from 218 more to 1000 more)	⊕⊕OO LOW	IMPORTANT
								0%		-		
Parent Preferences (assessed with: questionnaire about parent use of tactile stimulation again in the future, yes/no)												
1	randomised trials	serious[6,11]	no serious inconsistency	no serious indirectness	serious[12]	none	-	-	-[13]	-	⊕⊕OO LOW	IMPORTANT
								0%		-		
Fear, Procedure Outcomes, Vaccine Compliance, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

[1] The study by Chung (2002) was a cross-over trial

[2] Immunizers, parents, children/adult participants not blinded; outcome assessor not blinded; quasi-randomization and unclear randomization

[3] Unclear risk of performance bias (e.g., positioning of child in study by Sparks (2001), order of injection/vaccine used in study by Chung (2002))

[4] Both intramuscular and subcutaneous injections included

[5] Confidence interval crosses the line of nonsignificance

[6] In 1 study (Hogan 2014), contamination may have occurred due to positioning technique used

[7] In study by Hogan (2014), parent provided tactile stimulation. Removal of the data from this study yields an SMD = -1.20 (95% CI -2.49 to 0.08)

[8] Immunizers not blinded; outcome assessor not consistently blinded; unclear risk of bias due to contamination (in 1 study by Hogan (2014), infant positioning may have led to tactile stimulation in the no treatment group)

[9] Heterogeneity may be explained by differences in concomitant therapy (in the studies by Hogan 2014 and Taddio 2014, sucrose and infant holding were co-interventions) and differences in the delivery of the tactile stimulation, including technique (tapping vs. rubbing) and operator (parent vs. immunizer). Removal of the data from Hogan (2014) whereby rubbing was delivered by a parent does not alter the meta-analytic result; pain scores are not statistically lower for the intervention (tactile stimulation) group (SMD = -1.20 (95% CI -2.49 to 0.08).

[10] Confidence interval crosses line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

[11] Immunizer not blinded; however, parents and outcome assessor blinded

[12] Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

[13] In the tactile stimulation group, 53/60 (88%) of parents stated they would use tactile stimulation again in the future. In the entire study sample (n=120), 105/120 (88%) of parents stated they would use sucrose again and 103/120 (86%) stated they would use distraction again